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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,798	10/18/2005	Satoshi Yoshida	07580.0008	6122

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EXAMINER	
CHEN, CATHERYNE	

ART UNIT	PAPER NUMBER
1655	

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01/15/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,798	YOSHIDA ET AL.	
	Examiner	Art Unit	
	CATHERYNE CHEN	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2 and 3* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Currently, Claims 2-3 are pending. Claims 2-3 are examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

Claim Rejections - 35 USC § 103

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamanouchi (JP 2000281584 A with translation provided) in view of Levine et al. (1989, Int Conf AIDS, 5, 406), Nissen et al. (1988, Blood, 72, 2045-2047) and Weisbart et al. (1985, Nature, 314, 361-363) for the reasons set forth in the previous Office Action, which is set forth below. All of Applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive.

Yamanouchi teaches neutrophil activator consists of pumpkin seed is also known as Cucurbita moschata (see http://www.tropilab.com/cucur-max.html), safflower is also known as Carthmus tinctorius (see http://www.uni-graz.at/~katzer/engl/Cart_tin.html), plantago (Plantago asiatica), and Lonicera japonica (Abstract). 5.0 g or 41.67% of Japanese pumpkin seed, 3.0 g or 25% of safflower, 1.0 g or 8.33% of psyllium is also known as Plantago asiatica (see http://www.herbalremedies.com/psylliumhusk.html), 3.0 g or 25% of Japanese honeysuckle is also known as Lonicera japonica (see

http://plants.usda.gov/java/profile?symbol=LOJA). The gram weights can be expressed as percentage by dividing the weight of each plant by the total amount. However it does not teach a method of treating neutropenia.

Levine et al. teaches use of GM-CSF for patients with neutropenia (Abstract).

Weisbart et al. teaches GM-CSF is a neutrophil-activating factor (Abstract, last sentence).

Cucurbita moschata, Carthmus tinctorius, Plantago asiatica, and Lonicera japonica are neutrophil activators. Neutrophil activators, exemplified by GM-CSF, can be used to treat patients with neutropenia. Thus, an artisan of ordinary skill would reasonably expect that the composition of Yamanouchi could be used to treat neutropenia because neutrophil activator is used to treat neutropenia. This reasonable expectation of success would motivate the artisan to use the claimed ingredients in the reference composition to treat neutropenia. Thus, using the claimed ingredients in the reference composition to treat neutropenia is considered an obvious modification of the references.

Applicant argues that there is no reason to combine the references.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re*

Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Cucurbita moschata, Carthmus tinctorius, Plantago asiatica, and Lonicera japonica are neutrophil activators. Neutrophil activators, exemplified by GM-CSF, can be used to treat patients with neutropenia. Thus, an artisan of ordinary skill would reasonably expect that the composition of Yamanouchi could be used to treat neutropenia because neutrophil activator is used to treat neutropenia.

Applicant argues that neutrophil activation will not lead to treatment of neutropenia.

In response to Applicant's argument, the fact that Yamanouchi teaches the amounts of the claimed ingredients, which are neutrophil activators, and neutrophil activation can lead to treatment of neutropenia, then there is reason to conclude that ingredients taught by Yamanouchi can be used to treat neutropenia.

Applicant argues mechanism of treating neutropenia is not the same.

In response to Applicant's argument, a disclosure of the exact mechanism of action is not required. The reference specifically claims using the claimed ingredients in a composition as neutrophil activators. The reference gives the activity and the appropriate dosage amount. Therefore, an artisan of ordinary skill would clearly see that this reference shows that using the claimed ingredients was known in the art at the time of the invention.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamanouchi (JP 2000281584 A with translation provided) in view of Kojima et al. (1991, Blood, 77, 937-941) and Falanga et al. (1999, Blood, 93, 2506-2514) for the reasons set

forth in the previous Office Action, which is set forth below. All of Applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive.

Yamanouchi teaches neutrophil activator consists of pumpkin seed is also known as Cucurbita moschata (see http://www.tropilab.com/cucur-max.html), safflower is also known as Carthmus tinctorius (see http://www.uni-graz.at/~katzer/engl/Cart_tin.html), plantago (Plantago asiatica), and Lonicera japonica (Abstract). 5.0 g or 41.67% of Japanese pumpkin seed, 3.0 g or 25% of safflower, 1.0 g or 8.33% of psyllium is also known as Plantago asiatica (see http://www.herbalremedies.com/psylliumhusk.html), 3.0 g or 25% of Japanese honeysuckle is also known as Lonicera japonica (see http://plants.usda.gov/java/profile?symbol=LOJA). The gram weights can be expressed as percentage by dividing the weight of each plant by the total amount. However it does not teach a method of treating aplastic anemia.

Kojima et al. teaches the increase of neutrophil count is effective as treatment of aplastic anemia by administrating G-CSF in patients (Introduction).

Falanga et al. teaches G-CSF has neutrophil activating effect (page 2506, Introduction, left column, paragraph 2).

Cucurbita moschata, Carthmus tinctorius, Plantago asiatica, and Lonicera japonica are neutrophil activators. Neutrophil activators, exemplified by G-CSF, can be used to treat patients with aplastic anemia. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use ingredients that can activate neutrophils because neutrophil activators can be used to treat aplastic anemia. One would have been motivated to use the composition for the expected benefit of

treating aplastic anemia. Absent evidence to the contrary, there would have been a reasonable expectation of success in making the claimed invention from the combined teachings of the cited references.

Applicant argues that there is no reason to combine the references.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Cucurbita moschata, Carthmus tinctorius, Plantago asiatica, and Lonicera japonica are neutrophil activators. Neutrophil activators, exemplified by G-CSF, can be used to treat patients with aplastic anemia. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use ingredients that can activate neutrophils because neutrophil activators can be used to treat aplastic anemia.

Applicant argues that neutrophil activation will not lead to treatment of aplastic anemia.

In response to Applicant's argument, the fact that Yamanouchi teaches the amounts of the claimed ingredients, which are neutrophil activators, and neutrophil activation can lead to treatment of aplastic anemia, then there is reason to conclude that ingredients taught by Yamanouchi can be used to treat aplastic anemia.

Applicant argues mechanism of treating aplastic anemia is not the same.

In response to Applicant's argument, a disclosure of the exact mechanism of action is not required. The reference specifically claims using the claimed ingredients in a composition as neutrophil activators. The reference gives the activity and the appropriate dosage amount. Therefore, an artisan of ordinary skill would clearly see that this reference shows that using the claimed ingredients was known in the art at the time of the invention.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERYNE CHEN whose telephone number is (571)272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Catheryne Chen
Examiner Art Unit 1655

/Michele Flood/
Primary Examiner, Art Unit 1655